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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,554	02/04/2006	Jeroen Alphons Tonnaer	2003-793US	2808
67706	7590	06/15/2009		
ORGANON USA, INC. c/o Schering-Plough Corporation 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033			EXAMINER	KIM, JENNIFER M
		ART UNIT	PAPER NUMBER	
		1617		
		NOTIFICATION DATE	DELIVERY MODE	
		06/15/2009	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jill.corcoran@spcorp.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/560,554	<b>Applicant(s)</b> TONNAER, JEROEN ALPHONS
	<b>Examiner</b> JENNIFER MYONG M. KIM	<b>Art Unit</b> 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 February 2006.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 2/4/2006

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### **Claims 1-20 are presented for Examination.**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-20 provide for the use of an antipsychotic agent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delbressine et al. (U.S.Patent No. 5,763,476) of record in view of Aronne (2001) and further in view of Alexander-Bridges et al. (U.S.Patent No. 5,496,831).

Delbressine et al. teach that a composition comprising Org 5222 (also known as asenapine maleate) useful for the treatment of mental disorder such as schizophrenia. Delbressine et al. teach that the composition can be administered sublingually. (abstract, claims 1 and 4).

Delbressine et al. do not teach that the schizophrenic patients disclosed by Delbressine et al. is overweight, the cause of the weight gain, the protection against

weight increase and cause of the weight increase due to risk factors and overweight defined limits set forth in claims 4 and 5.

Aronne teaches that the rate of patients with schizophrenia comorbid with obesity is higher compared to the general population. (abstract).

Alexander-Bridges et al. teach that obesity can be measured by determining the body mass index (BMI) which is the ratio of the weight (kg) to the square of the height (m) of the subject. The treatment to decrease body fat is generally recommended for women with a BMI of above 27, and men with a BMI above 28. (column 5, lines 55-66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Org 5222 (also known as asenapine maleate) to schizophrenic patients comorbid with obesity. One would have been motivated to make such a modification because in general, the rate of a patient with schizophrenia comorbid with obesity is higher than the general population and because Delbressine et al. teach that asenapine is useful for the treatment of schizophrenia in general. One would make such a modification in order to achieve a beneficial effect of asenapine in treatment of schizophrenia inclusive of those comorbid with obesity. There is a reasonable expectation of success in treatment of schizophrenia in a patient with overweight problems like obesity because the effectiveness of asenapine in treatment of schizophrenia would be retained regardless of their weight.

With regard to the definition of overweight set forth in claims 4 and 5, such are obvious requirement because Alexander-Bridges et al. teach that obesity can be measured by determining the body mass index (BMI) which is the ratio of the weight

Art Unit: 1617

(kg) to the square of the height (m) of the subject. The treatment to decrease body fat is generally recommended for women with a BMI of above 27, and men with a BMI above 28 as well known.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/  
Primary Examiner, Art Unit 1617

Jmk  
May 29, 2009

Application/Control Number: 10/560,554

Page 7

Art Unit: 1617